Exactech® Gibralt® Occipital Spine System
Traditional 510(k)

510(k) Summary

FEB 1 2 2013

Company: Exactech®, Inc
2320 NW 66th Court
Gainesville, FL 32653

Date: January 14, 2013

Contact Person: Vladislava Zaitseva
Sr. Regulatory Affairs Specialist

Phone: (352) 377-1140
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Proprietary Name: Exactech® Gibralt® Occipital Spine System

Common Name: Occipital Plate System

Classification Name: Appliance, fixation, spinal interlaminal

Product Code: KWP

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- DePuy Mountaineer OCT Spinal System (K110353, K042508, and K041203)
- Medtronic Vertex Select Reconstruction System (K110522, K091365, K090714, and K082728)
- Zimmer (Abbott Spine) Nex-Link OCT Cervical Plating System (K090060)

Device Description

The Gibralt Occipital Spine System is a new posterior system intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the occipital-cervical-thoracic region of the spine.

The system consists of a variety of sizes of the occipital plates and occipital bone screws, and articulating rod and set screws. All components of the system are manufactured from titanium alloy per ASTM F136.

The Gibralt Occipital system should be used in conjunction with the Gibralt Spine System components such as hooks, polyaxial screws and connecting components. The Gibralt Spine System has been cleared by FDA through 510(k) # K110197 on July 15, 2011.

The Gibralt Occipital Spine System is provided with a complete instrumentation system to assist the surgeon in the implantation of the components according to a traditional open surgical procedure.

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Indications for Use
When used with the Gibralt Spine System, the Gibralt Occipital Spine System is intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput - T3). The Gibralt Occipital Spine System is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture/dislocation, occipital-cervical dislocation, atlanto-axial fracture with instability, failed previous fusion and/or tumors.

The Occipital Bone Screws are limited to occipital fixation only.

The use of polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. Polyaxial screws are not intended to be placed in the cervical spine.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following characteristics:

- *Intended Use/Indications for Use*
  The proposed Gibralt Occipital Spine System and predicates have similar indications for use statements.

- *Materials*
  The proposed Gibralt Occipital Spine System components and predicate devices are composed of titanium alloy, a biocompatible material conforming to a recognized industry standard for permanent implants.

- *Design Features*
  The proposed Gibralt Occipital Spine System components and predicate devices have similar design features.

- *Dimensions*
  The proposed Gibralt Occipital Spine System components and predicate devices are dimensionally comparable.

- *Packaging and Sterilization*
  The proposed Gibralt Occipital Spine System components and predicate devices are provided non-sterile for single use only, and will be steam sterilized by the hospital prior to use in the operating room using the same sterilization method.

- *Device Shelf Life*
  Neither the Gibralt Occipital Spine System components nor cited predicate devices have shelf life expiration dating.

- *Performance specifications*
  The Gibralt Occipital Spine System and cited predicates all withstand clinically relevant biomechanical loads.

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Substantial Equivalence Conclusion
The following mechanical testing and engineering analyses were conducted to demonstrate substantial equivalence of the proposed Gibralt Occipital Spine System to cited predicates:

- Static Compression Bend, Dynamic Compression Bend, Static Yield Torsion, Dynamic Torsion, Axial Pullout and Static Torque testing per ASTM F2706 and ASTM F543.

- A biomechanical assessment comparing Gibralt Occipital Spine System mechanical performance and design features to cited predicate devices.

The results of mechanical testing and analysis demonstrate the proposed device is substantially equivalent to cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Exactech®, Incorporated
% Travis Arola, MS, RAC, CTBS
Director, Regulatory, Spine & Biologics
2320 Northwest 66th Court
Gainesville, Florida 32653

Letter dated: February 12, 2013

Re: K121877
Trade/Device Name: Exactech® Gibralt® Occipital Spine System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: January 14, 2013
Received: January 16, 2013

Dear Mr. Arola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number: K121877

Device Name: Exactech® Gibralt® Occipital Spine System

INDICATIONS FOR USE:
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Prescription Use __X__ **and/or** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line – use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K121877